Kentucky Department for Medicaid Services

Drug Review Options

The following chart lists the agenda items scheduled and the options submitted for review at the September 16, 2004, meeting of the Pharmacy and Therapeutics Advisory Committee.

Item	Options for Consideration
Fluoroquinolone Antibiotic Therapeutic Class Review	1. Trovafloxacin (Trovan®) is not essential. Trovafloxacin is highly restricted because of its high incidence of hepatoxicity. 2. Norfloxacin is not essential. It does not achieve high serum concentrations, and therefore, is not indicated for infections outside the genitourinary tract. 3. Lomefloxacin is not essential due to safety concerns without off-setting clinical advantage. 4. No one fluoroquinolone will be appropriate for all patients or all infections. However, for purposes of this review process, the remaining fluoroquinolones are rated as equivalent, with the following considerations: a. For gram negative coverage, the PDL should include a fluoroquinolone with adequate coverage for *Pseudomonas aeruginosa*. Prefer at least one antibiotic from the following group based on lowest net cost: ciprofloxacin (Cipro), ofloxacin (Floxin) or levofloxacin (Levaquin). Additionally, required prior authorization for all branded forms of ciprofloxacin including Cipro XR. b. For gram-positive, anaerobic and miscellaneous coverage, the PDL should include a fluoroquinolone with enhanced coverage of these bacteria. Prefer at least one antibiotic from the following group based on lowest net cost: gatifloxacin (Tequin), levofloxacin (Levaquin), moxifloxacin (Avelox), or gemifloxacin (Factive). 5. For any new chemical entity in the fluoroquinolone antibiotic class require a PA and quantity limit until reviewed by the P&T advisory Committee.
Nasal Inhaled Corticosteroids Therapeutic Class Review	1. The nasal corticosteroids are clinically equivalent. 2. Choose at least two preferred products based on lowest net cost with PA required for non-preferred products based on failure or contraindication of a preferred product. 3. Place a quantity limit of one inhaler unit per 30 day supply. 4. For any new chemical entity in the nasal corticosteroid class require a PA and quantity limit until reviewed by the P&T advisory Committee.

Benign Prostatic Hypertrophy Disease Management Review	1. The alpha-blockers are considered to be equivalent for safety and efficacy. 2. The 5-alpha reductase inhibitors are considered to be equivalent for safety and efficacy. 3. Select at least one alpha-blocker for the PDL based on lowest effective net cost. 4. Prior authorize the 5-alpha reductase inhibitors and select at least one (1) for the PDL based on lowest effective net cost. 5. For any new chemical entity in the alpha-blocker or 5-alpha reductase inhibitor class, require a PA and quantity limit until reviewed by the P&T Advisory Committee.

The following terms will be utilized within the therapeutic monograph to classify medications during Drug Class Reviews. By using these terms, the reviewer will be able to easily identify any clinical differences between the medications within the class being reviewed.

Superior - Following evidence-based review, it is determined that the drug provides a therapeutic advantage, in terms of safety and/or efficacy, over other available products within the same treatment modality.

Novel - Following evidence-based review, the drug is therapeutically equivalent in both safety and efficacy, but represents a new therapeutic option, which expands the treatment modality.

Equivalent - Following evidence-based review, it is determined that the drug is therapeutically equivalent in both safety and efficacy to other available products within the same treatment modality.

Not Essential - Following evidence-based review, it is determined that the drug has no therapeutic advantage, due to either reduced safety or efficacy, over other available products within the same treatment modality.

Asthma Disease Management Review	1. All short acting Beta-agonist agents are equivalent in efficacy and safety with the exception of metaproteranol when administered at comparable doses and all long acting Beta-agonist agents are equivalent in efficacy and safety when administered at comparable doses. 2. All inhaled oral corticosteroids are equivalent in efficacy when administered at comparable doses. 3. An oral extended-release formulation of albuterol should be available for those patients who cannot tolerate or use an inhaled long-acting beta-agonist agent. 4. Due to efficacy and safety concerns place a PA on metaproteranol (short acting beta-agonists). 5. Select at least one (1) of the other short acting Beta-agonist to be on the PDL. 6. Require PA for Xopenex. 7. Select at least two (2) oral inhaled corticosteroids (single entity and combination products) to be on the PDL. 8. Continue prior authorization for Xolair using current criteria from the September 18, 2003 P&T meeting. 9. For any new chemical entity in the Beta-agonist or oral corticosteroids class, require a PA and quantity limit until reviewed by the P&T Advisory Committee.
Erectile Dysfunction Disease State Management Review	1. The PDE5 inhibitors (Viagra, Levitra, Cialis) are considered to be equivalent in safety and efficacy. 2. The Alprostadil agents (Caverject, Edex) are considered to be equivalent in safety and efficacy. Muse is not as well tolerated as the other two agents and is more likely to cause systemic effects such as hypotension. 3. All the testosterone agents are considered to be equivalent in safety and efficacy. 4. Yohimbine is non-essential. 5. Limit quantities to a total of 4 units per month for any of the PDE5 inhibitors and Alprostadil agents. 6. Limit treatment to males only for PDE5 inhibitors, alprostadil agents, and testosterone agents. 7. Select at least one agent from the PDE5 inhibitors and alprostadil groups to be on the PDL based on lowest net cost. 8. Retain current PA status for testosterone and yohimbine agents. 9. For any new chemical entity in the ED class require a PA and quantity limit until reviewed by the P&T advisory Committee.